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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/659,684 | 09/10/2003 | Julia E. Novak | 99-16C1 | 6041 |

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| EXAMINER |
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SEHARASEYON, JEGATHEESAN

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| ART UNIT | PAPER NUMBER |
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1647

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09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,684

Applicant(s)

NOVAK ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's remarks and amendments filed 6/26/2007. Applicant's have cancelled claim 12-47. Claims 1-7 and 9-11 are pending and examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

3. The Office notes that Applicant has amended the specification to remove embedded hyperlinks and capitalize trademarks.

4. The Office acknowledges the receipt of the terminal disclaimer against 6, 307, 024.

Claim Rejections - 35 USC § 112, 1st paragraph maintained

5a. The rejection of claims 1-7 and 9-11 under 35 U.S.C. 112, first paragraph, because the specification while enabling for SEQ ID NO: 2, does not reasonably provide enablement for all possible fragments and variants including those that are at least 90% or 95% identical to fragments of SEQ ID NO: 2 is maintained for reasons set forth in the Office Action dated 1/17/07 pages 3-7. Specifically, claims 1-3, 5-7 and 9-11 recite the phrase "a polypeptide" and thus, are broadly interpreted by the Examiner as reading upon: (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2, including sequences only 6 amino acids in length (see specification page 56).

Applicant is essentially arguing that the Office is interpreting the claims more broadly compared to the interpretation of the claims accepted by the Office previously

Art Unit: 1647

including those that were accepted in the Patent (U.S. Patent No. 6, 307, 024) used for nonstatutory obviousness-type double patenting rejection. Applicant is arguing that the broadest possible interpretation of language is not necessarily the broadest reasonable interpretation. Applicant contends that the USPTO's new interpretation of the contested language of the claims renders the claim so broad as it reads on any amino acid sequence that has six or more residues. Applicant argues that this interpretation is unreasonable. In addition, such an interpretation of the claims is entirely inconsistent with the specification, and hence cannot be reasonable. In addition, Applicant asserts that support for such an interpretation is not found in the application, for the simple reason that applicants never intended to make such a claim and therefore never described or enabled amino acid sequences that were six or more amino acid residues long. Further it is asserted that it is difficult to understand why an interpretation that was reasonable has been replaced by an interpretation that is contrary to the specification and claims of the patent. Applicant discusses the Office interpretation of the claims extensively on pages 7-10 of the response, specifically the inclusion of the fragments and variants. Applicant asserts that they describe the claimed fragments and variants both structurally and functionally. Applicant also discusses various fragments that are claimed and the biological function of the polypeptides (see page 9 of the response). Applicant's arguments have been fully considered but are not found to be persuasive.

With respect to Applicant's assertion that the Office is interpreting the claims more broadly compared to the interpretation of the claims previously acceptable to the Office including U.S. Patent No. 6, 307, 024, this is not the same application and we do

Art Unit: 1647

not comment on what was previously done in another case. Specifically each case is examined on its own merits. Contrary to Applicant's assertion that Office interpretation is unreasonable, the Office is interpreting "a" as an indefinite article to read on (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2. In contrast "the" is considered definite article and thus is interpreted to be limited to the sequence of interest only. In addition, the specification of the instant invention defines a polypeptide as a polymer of amino acid residues joined by peptide bonds, whether produced naturally or synthetically. Further, the specification teaches that polypeptides of less than about 10 amino acid residues are commonly referred to as "peptide". Although, the specification clearly identifies various fragments, the Office is interpreting the claims to read on for example, polypeptide fragment and variants that are 6 amino acids or longer because of the indefinite article "a". In addition, there is no enabling disclosure for variants that 90% or 95% identical to mature polypeptide or the polypeptide fragments. Although, the specification discloses the biological function of the α 11 ligand are disclosed, there is no correlation between the various variants and the biological functions disclosed. In the absence of further guidance, these experiments (assay for proliferation, binding assays etc.) would be more than routine experimentation for one of skilled in the art. It will require trial and error experimentation to identify the variants that are functional. Therefore, the rejection of record is maintained.

5b. The rejection of claims 1-7 and 9-11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1647

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection* is maintained for reasons set forth in the Office Action dated 1/17/07 pages 7-9. The specification does not disclose all possible variants including those that are at least 90% or 95% identical to fragments of SEQ ID NO: 2 or fragments of SEQ ID NO: 2 contemplated by the Applicant. Specifically, claims 1-3, 5-7 and 9-11 lack written description support for the language reciting the phrases and "a polypeptide" and thus, are broadly interpreted by the Examiner as reading upon: (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2, including sequences only 6 amino acids in length (see specification page 56).

Applicant has argued both the enablement and written description together (see 4a). Applicant's arguments have been fully considered but are not found to be persuasive. The Office has responded to the Applicant's arguments above in paragraph 4a. Therefore, the rejection of record is maintained.

5c. The rejection of claims 9-11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition of polypeptide of SEQ ID NO: 2 or polypeptide comprising residues 32 to 162 of SEQ ID NO: 2 (alpha11 ligand) does not reasonably provide enablement for pharmaceutical composition comprising polypeptide that is 90% or 95% identical to residues 32 to 162 of SEQ ID NO: 2 or residues 32 to 162 of SEQ ID NO: 2 is maintained for reasons set forth in Office Action

Art Unit: 1647

dated 1/17/07 pages 9-10. Applicant has not traversed the rejection. Therefore, the rejection of record is maintained.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6a. The provisional rejection of claims 1-7 and 9-11 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 and 9-11 of copending Application No. 11/ 551, 807 is maintained for reasons set forth in Office Action dated 1/17/07 page 12. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant's arguments are noted, however, since claims are not allowable the rejection is maintained.

Conclusion

7. No claims are allowable.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1647

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/659,684

Page 8

Art Unit: 1647

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS

Art Unit 1647,
September 4th, 2007.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud